UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
EVANSVILLE DIVISION

BARBARA HULL,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 3:20-cv-00038-JMS-DML
	)	
ETHICON, INC. and JOHNSON & JOHNSON,	)	
	)	
Defendants.	)	

ORDER

Plaintiff Barbara Hull initiated this litigation in September 2014 by filing a Short Form Complaint as part of *In re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation*, MDL No. 2327, a multidistrict litigation pending in the United States District Court for the Southern District of West Virginia (the "MDL"). On January 9, 2020, Ms. Hull's case was transferred from the MDL to this Court because "the time to conduct discovery is complete…, and the parties have had time to file dispositive and *Daubert* motions, responses and replies," and "the cases would be more expeditiously concluded in the venues from which they arise." [Filing No. 35 at 1.] A Motion for Partial Summary Judgment filed by Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson in the MDL is ripe for this Court's decision. [Filing No. 23.]

I.
STANDARD OF REVIEW

A motion for summary judgment asks the Court to find that a trial is unnecessary because there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). As the current version of Rule 56 makes clear, whether a party asserts that a fact is undisputed or genuinely disputed, the party must support the asserted fact by citing to particular parts of the record, including depositions, documents, or affidavits. Fed.

R. Civ. P. 56(c)(1)(A). A party can also support a fact by showing that the materials cited do not establish the absence or presence of a genuine dispute or that the adverse party cannot produce admissible evidence to support the fact. Fed. R. Civ. P. 56(c)(1)(B). Failure to properly support a fact in opposition to a movant's factual assertion can result in the movant's fact being considered undisputed, and potentially in the granting of summary judgment. Fed. R. Civ. P. 56(e).

In deciding a motion for summary judgment, the Court need only consider disputed facts that are material to the decision. A disputed fact is material if it might affect the outcome of the suit under the governing law. *Hampton v. Ford Motor Co.*, 561 F.3d 709, 713 (7th Cir. 2009). In other words, while there may be facts that are in dispute, summary judgment is appropriate if those facts are not outcome determinative. *Harper v. Vigilant Ins. Co.*, 433 F.3d 521, 525 (7th Cir. 2005). Fact disputes that are irrelevant to the legal question will not be considered. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

On summary judgment, a party must show the Court what evidence it has that would convince a trier of fact to accept its version of the events. *Johnson v. Cambridge Indus.*, 325 F.3d 892, 901 (7th Cir. 2003). The moving party is entitled to summary judgment if no reasonable fact-finder could return a verdict for the non-moving party. *Nelson v. Miller*, 570 F.3d 868, 875 (7th Cir. 2009). The Court views the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *Darst v. Interstate Brands Corp.*, 512 F.3d 903, 907 (7th Cir. 2008). It cannot weigh evidence or make credibility determinations on summary judgment because those tasks are left to the fact-finder. *O'Leary v. Accretive Health, Inc.*, 657 F.3d 625, 630 (7th Cir. 2011). The Court need only consider the cited materials, Fed. R. Civ. P. 56(c)(3), and the Seventh Circuit Court of Appeals has "repeatedly assured the district courts that they are not required to scour every inch of the record for evidence that is potentially relevant to

the summary judgment motion before them." *Johnson*, 325 F.3d at 898. Any doubt as to the existence of a genuine issue for trial is resolved against the moving party. *Ponsetti v. GE Pension Plan*, 614 F.3d 684, 691 (7th Cir. 2010).

II.
STATEMENT OF FACTS

The following factual background is set forth pursuant to the standards detailed above. The facts stated are not necessarily objectively true, but as the summary judgment standard requires, the undisputed facts and the disputed evidence are presented in the light most favorable to "the party against whom the motion under consideration is made." *Premcor USA, Inc. v. American Home Assurance Co.*, 400 F.3d 523, 526-27 (7th Cir. 2005).

A. Ms. Hull's Medical History

Ms. Hull is a 58 year-old woman who lives in Illinois.[1] [Filing No. 3 at 1.] On January 24, 2008, Ms. Hull underwent a surgical procedure whereby a TVT-Secur transvaginal mesh device ("TVT-S") was implanted. [Filing No. 27-2 at 2.] The surgery took place at Deaconess Women's Hospital in Newburgh, Indiana, and was performed by Dr. Cindy Basinski. [Filing No. 27-2 at 2.] Prior to her surgery, Ms. Hull had been diagnosed with various medical conditions including pelvic organ prolapse and stress urinary incontinence, and the surgery was aimed at addressing those issues. [Filing No. 27-2 at 2.]

Dr. Basinski testified that she does not recall whether she reviewed the Instructions For Use ("IFU") for the TVT-S, and it is possible she reviewed it and possible she did not review it.

[1] After Ms. Hull's case was transferred here, the Court confirmed that it has diversity jurisdiction over this matter. [*See* Filing No. 48 (Court's Order requiring parties to file a Joint Jurisdictional Statement setting forth their respective citizenships and the amount in controversy); Filing No. 52 (Joint Jurisdictional Statement); and Filing No. 53 (Court's Order accepting the Joint Jurisdictional Statement as sufficient to establish diversity jurisdiction at this time).]

[Filing No. 23-1 at 29.] Dr. Basinski also testified that she did not rely on Ethicon to tell her the risks associated with pelvic floor surgery, or the risks associated with the TVT-S. [Filing No. 23-1 at 29-30.] She testified that before Ms. Hull's surgery, she was aware of many potential risks and complications associated with the use of the TVT-S, including chronic pain, pelvic organ prolapse, chronic dyspareunia, mesh erosion, bleeding, wound complications, new or worsening urinary symptoms such as retention or overactive bladder, failure of the surgery to treat incontinence, organ or nerve damage, fistula formation, infection, foreign body response to the mesh, vaginal scarring, and contraction of tissue associated with scarring. [Filing No. 23-1 at 28.] Dr. Basinski testified that if Ethicon had listed each of these risks in the IFU, it would not have affected her decision to recommend the TVT-S to Ms. Hull because "those were known risks with any midurethral sling procedure." [Filing No. 23-1 at 30.]

Several years after the January 24, 2008 surgery, Ms. Hull was diagnosed with vaginal mesh erosion and underwent a procedure for "excision of vaginal mesh erosion" on July 19, 2014. [Filing No. 27-2 at 4.][2] The procedure was performed by Dr. Richard Sandefur. [Filing No. 27-2

[2] In her response to the Partial Motion for Summary Judgment, Ms. Hull states that she "developed complications from Defendants' defective transvaginal mesh device," including "recurrent urinary tract infections, chronic vaginal discharge, dyspareunia, and a mesh erosion, which required a surgical excision performed on July 19, 2013," and cites to her medical records. [Filing No. 28 at 2.] But the medical records she cites to only state that she was diagnosed with vaginal mesh erosion and that an excision of vaginal mesh erosion was performed, along with a description of the procedure. [Filing No. 27-2 at 4.] Because Ms. Hull has not cited to record evidence which reflects the multiple complications she mentions and which attributes those complications to the TVT-S, the Court cannot consider that information in ruling on the Partial Motion for Summary Judgment.

at 4.][3]

B. The Litigation

Ms. Hull initiated this litigation on September 30, 2014 by filing a Short Form Complaint, [Filing No. 1], and filed the operative Amended Short Form Complaint on October 2, 2014, [Filing No. 3]. She asserts the following claims:

- Count I – Negligence;
- Count II – Strict Liability – Manufacturing Defect;
- Count III – Strict Liability – Failure to Warn;
- Count IV – Strict Liability – Defective Product;
- Count V – Strict Liability – Design Defect;
- Count VI – Common Law Fraud;
- Count VII – Fraudulent Concealment;
- Count VIII – Constructive Fraud;
- Count IX – Negligent Misrepresentation;
- Count X – Negligent Infliction of Emotional Distress;
- Count XI – Breach of Express Warranty;
- Count XII – Breach of Implied Warranty;
- Count XIII – Violation of Consumer Protection Laws;

[3] Ms. Hull states in her response brief that she "will continue to have complications from the mesh into the future," and cites generally to the Expert Report of Dr. James Wheeler. [Filing No. 28 at 2.] Aside from the unhelpfulness of citing generally to a twenty-two page report, *see Johnson*, 325 F.3d at 898 (district court need not "scour every inch of the record for evidence that is potentially relevant to the summary judgment motion before them"), the Court has found in a separate Order entered this day that Dr. Wheeler's case-specific conclusions must be excluded and may not be relied upon in this litigation.

- Count XIV – Gross Negligence;
- Count XV – Unjust Enrichment;
- Count XVII[4] – Punitive Damages; and
- Count XVIII – Discovery Rule and Tolling.

Filing No. 3 at 4-5.] Defendants move for summary judgment on all of Ms. Hull's claims except for her negligent design defect theory, Count XVII (Punitive Damages), and Count XVIII (Discovery Rule and Tolling). [Filing No. 23.]

III.
DISCUSSION

The Court notes at the outset that the parties have submitted very little evidence in connection with Defendants' Partial Motion for Summary Judgment. The Court understands that this matter was part of the MDL, a procedure that may have affected the volume of information submitted by the parties. That said, the Court can only base its ruling on the record before it and can only consider facts which are supported by citations to that record.

A. Ms. Hull's Concessions

In her response to Defendants' Partial Motion for Summary Judgment, states that she does not oppose Defendants' motion as to Counts II, IV, VI, VII, VIII, IX, X, XI, XII,[5] XIII, XIV, and XV. [Filing No. 28 at 3.] Accordingly, the Court **DISMISSES** those claims, and Defendants' Partial Motion for Summary Judgment as to those claims is **DENIED AS MOOT**.

[4] Ms. Hull did not place a check in the box next to "Count XVI - Loss of Consortium," listed on the Amended Short Form Complaint.

[5] Ms. Hull lists Count XIII twice in her recitation of the claims for which she does not oppose summary judgment. The first time she lists Count XIII, she describes it as "Breach of Implied Warranty." [Filing No. 28 at 3.] Because the Breach of Implied Warranty claim is actually Count XII, the Court assumes that Ms. Hull's first listing of Count XIII is a typographical error, and that Ms. Hull intended to list Count XII instead.

B. The Remaining Claims

Remaining for the Court's consideration are Count I (Negligence), Count III (Strict Liability – Failure to Warn), and Count V (Strict Liability – Design Defect). Ms. Hull also states that she will "pursu[e] at trial" her claims for punitive damages (Count XVII) and "Discovery Rule and Tolling" (Count XVIII). [Filing No. 28 at 3.]

As an initial matter, the Court finds that Count XVII for "Punitive Damages" and Count XVIII for "Discovery Rule and Tolling" are not separate causes of action or standalone claims. Rather, punitive damages is a remedy, and the discovery rule and tolling are defenses to a statute of limitations argument. Counts XVII and XVIII are **DISMISSED WITH PREJUDICE**.[6]

Defendants set forth the following arguments in their Partial Motion for Summary Judgment which are relevant to Ms. Hull's remaining claims: (1) Ms. Hull's three remaining claims should be merged into a single claim under the Indiana Products Liability Act, Ind. Code § 34-20-1-1, *et seq.* (the "IPLA")[7]; (2) Ms. Hull's strict liability - failure to warn and strict liability - design defect claims fail because the IPLA prohibits those claims; and (3) Ms. Hull's negligence claim fails because there is no evidence that a failure to warn caused Ms. Hull's injuries and her

[6] This ruling, however, should not be read as a decision on the propriety of a punitive damages recovery, but simply a ruling that there is no separate cause of action for "punitive damages." In addition, Ms. Hull retains her right to counter any statute of limitations argument on the basis of the discovery rule and tolling.

[7] Defendants assert that Indiana law applies to Ms. Hull's claims, [Filing No. 24 at 3-5], and Ms. Hull agrees, [Filing No. 28 at 5]. Absent a disagreement, the Court will apply Indiana law. *Mass. Bay Ins. Co. v. Vic Koenig Leasing*, 136 F.3d 1116, 1120 (7th Cir. 1998); *Wood v. Mid-Valley, Inc.*, 942 F.2d 425, 426-27 (7th Cir. 1991) ("The operative rule is that when neither party raises a conflict of law issue in a diversity case, the federal court simply applies the law of the state in which the federal court sits…. Courts do not worry about conflict of laws unless the parties disagree on which state's law applies. We are busy enough without creating issues that are unlikely to affect the outcome of the case (if they were likely to affect the outcome the parties would be likely to contest them)").

negligence claim against Ethicon fails because there is no expert or other evidence establishing that the TVT-S deviated from its intended design. [Filing No. 24 at 5-11.] The Court addresses each argument in turn.

1. Whether Ms. Hull's Remaining Claims Should be Merged Into a Single Claim Under the IPLA

Originally enacted in 1978 and expanded in 1995, the IPLA "codified the entire field of products liability" law in Indiana. *Weigle v. SPX Corp.*, 729 F.3d 724, 737 (7th Cir. 2013). The IPLA "governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. "A product can be defective within the meaning of the [IPLA] because of a manufacturing flaw, a defective design or a failure to warn of dangers while using the product." *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018). The Indiana Supreme Court has stated that it is "clear the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981). Perhaps recognizing that clarity, Ms. Hull concedes that her remaining claims are governed by the IPLA. [Filing No. 28 at 5-7.]

Less clear, however, is whether different theories of liability – here, negligence, strict liability for design defect, and strict liability for a failure to warn – should be considered one claim under the IPLA. While some federal district courts sitting in Indiana have "merged" multiple claims under the IPLA into a single count, *see, e.g.*, *Bledsoe v. Medtronic, Inc.*, 2020 WL 43107, at *3 (N.D. Ind. 2020), others have declined to do so, *see, e.g.*, *Fisk v. Medtronic, Inc.*, 2017 WL 4247983, at *4 (N.D. Ind. 2017). The Court finds that whether Ms. Hull's negligence, strict liability for design defect, and strict liability for a failure to warn claims are merged into one claim

at this point is a distinction without a difference. Indiana law provides multiple theories of recovery for products liability under the IPLA, and the Indiana Pattern Jury Instructions for civil cases contain separate instructions for each theory. *See* Ind. Code § 34-20-4-1, *et seq.*; *Campbell*, 109 N.E.3d at 956; Indiana Pattern Jury Instruction (Civil) Chapter 2100 (providing pattern instructions for manufacturing defects); Indiana Pattern Jury Instructions (Civil) Chapter 2300 (providing pattern instructions for design defects and failure to warn). Because Ms. Hull is pursuing separate theories, the Court will consider each of those theories separately at the summary judgment stage of the case. Whether they are treated as one claim based on three theories of liability or three claims each based on separate theories of liability is of no consequence.

2. Whether the Strict Liability for a Failure to Warn and Strict Liability for Design Defect Claims Are Viable Under the IPLA

Defendants argue that the IPLA "abolished strict liability claims for design defects or inadequate warnings." [Filing No. 24 at 6-7.] Defendants cite to Ind. Code § 34-20-2-2, which requires a showing that the manufacturer or seller "failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions." [Filing No. 24 at 7.]

In her response, Ms. Hull acknowledges the "exercise of reasonable care" standard in the IPLA, but argues that her expert, Dr. Bruce Rosenzweig, "has offered a wealth of expert opinions regarding the defective design of the TVT-S such that, at a minimum, a genuine issue of material fact exists for the jury to decide." [Filing No. 28 at 8.] Ms. Hull sets forth many of Dr. Rosenzweig's opinions which she contends support her design defect claim. [Filing No. 28 at 8-9.] As for her strict liability failure to warn claim, Ms. Hull argues that "there is ample evidence that Defendants failed to provide adequate warnings to implanting physicians, including Dr. Basinski, regarding the frequency, severity, and permanency of the known risks specific to the

TVT-S." [Filing No. 28 at 10-12.] Ms. Hull provides a summary of the testimony from Dr. Basinski's deposition and the opinions of Dr. Rosenzweig that she relies upon for her failure to warn claim, and concludes that "there is ample expert testimony that unquestionably creates genuine issues of material fact about Defendants' failure to warn on known, serious complications associated with their defective device." [Filing No. 28 at 10-11.] Finally, Ms. Hull argues that the evidence supports the conclusion that if she had been warned of the true risks associated with the TVT-S, she would not have consented to the TVT-S implantation surgery. [Filing No. 28 at 12-13.]

Defendants did not file a reply.

The IPLA "grounds design defect and failure to warn theories in negligence terms – requiring a user or consumer to 'establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions.'" *Warner-Borkenstein v. Am. Med. Sys., Inc.*, 2020 WL 364019, at *2 (N.D. Ind. 2020). Only a manufacturing defect theory – a theory Ms. Hull has conceded she is no longer pursuing in this case – "remains grounded in strict liability in the true sense." *Id.* Because Indiana law does not recognize "strict liability" design defect or failure to warn claims, the Court **GRANTS** Defendants' Partial Motion for Summary Judgment on those claims. The Court will, however, consider design defect and failure to warn theories under the umbrella of Ms. Hull's IPLA negligence claim.

3. Whether the Negligence Claim Under the IPLA Fails As a Matter of Law

a. Failure to Warn Theory

In connection with Ms. Hull's failure to warn theory, Defendants argue that Indiana has adopted the "learned intermediary doctrine," whereby "manufacturers of prescription medical

products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product." [Filing No. 24 at 7-8 (citation and quotation omitted).] They argue that if no alleged deficiency in Ethicon's warnings could have affected Dr. Basinski's recommendation and caused Ms. Hull's injury, then they are entitled to summary judgment. [Filing No. 24 at 8.] Defendants point to Dr. Basinski's deposition testimony that she was not sure whether she read the IFU for the TVT-S, and that she knew about numerous risks and complications associated with the TVT-S and inclusion of those risks in the IFU would not have changed her decision to recommend the TVT-S to Ms. Hull in 2008. [Filing No. 24 at 8-9.] Defendants argue that "[b]ecause Ms. Hull cannot show that her prescribing physician would have made a different prescribing decision if the TVT-S had been accompanied by different warnings, then [Ms. Hull] cannot establish proximate causation as a matter of law." [Filing No. 24 at 9.]

In her response, Ms. Hull points to the following opinions of Dr. Rosenzweig in support of her failure to warn claim:

- Ethicon's warnings and disclosures of adverse events in the TVT-S IFU have been inadequate based on the facts known to Ethicon since the predecessor to the TVT-S was first sold and marketed;

- Ethicon did not disclose information in the IFU regarding the old type of mesh (Prolene), which was unsuitable because it was too rigid, had small pores, was heavyweight, degraded over time, and caused chronic foreign body reactions, fibrotic bridging, and mesh contracture/shrinkage;

- The foreseeable risks of harm could have been reduced or avoided by providing reasonable instructions or warnings;

- Ethicon did not inform physicians and patients that Material Safety Data Sheets for the polypropylene resin used to manufacture polypropylene meshes warned against the use of the mesh in a permanently implanted medical device because it is incompatible with peroxides and caused sarcomas in laboratory rats;

- Ethicon did not properly inform physicians that toxicity testing of the polypropylene mesh revealed that it was cytotoxic;

- The promotional materials Ethicon sent to physicians related to the TVT-S were inaccurate and failed to reveal material information about complications/risks and conflict of interests regarding data; and

- Ethicon's collection and reporting of adverse events and complications is misleading, inaccurate, and incomplete.

[Filing No. 28 at 10-11.] Ms. Hull also points to evidence that she contends supports the notion that Defendants failed to adequately warn Dr. Basinski of the known risks associated with the TVT-S, including Dr. Basinski's testimony that:

- She had no information regarding Ethicon declining offers from key opinion leaders to conduct pre-market, randomized control trials on the TVT-S;

- She had no recollection of being told by anyone at Ethicon that studies showed substantially high mesh exposure and erosion rates associated with the TVT-S as opposed to an older version of the TVT;

- She had no information from Ethicon regarding tips and tricks being offered to surgeons as early as 2007 relating to the TVT-S; and

- She was not aware that Ethicon voluntarily withdrew the TVT-S from the continent of Australia in 2007.

[Filing No. 28 at 11-12.] Finally, Ms. Hull notes her own testimony at her deposition that if she had been informed of the "true risks" associated with the TVT-S, she would not have had the TVT-S implantation surgery. [Filing No. 28 at 12-13.]

Indiana Code § 34-20-2-2 provides that "the party making the [failure to warn] claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in….providing the warnings or instructions." A claim of negligence based on a failure to warn requires proof that the defendant "breached the duty of reasonable care owed to [her]…and the breach proximately caused [her] injury." *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1008 (7th Cir. 2020). In Indiana, a defendant has "a duty to warn with respect to latent dangerous characteristics of the product, even though there is no 'defect' in the product itself." *Nat. Gas*

Odorizing, Inc. v. Downs, 685 N.E.2d 155, 161 (Ind. Ct. App. 1997). Under the learned intermediary doctrine, "the manufacturer of a…medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018); *Gore v. Stryker Corp.*, 2011 WL 13324116, at *1 (S.D. Ind. 2011) ("Indiana has adopted the learned intermediary doctrine in medical device cases. Pursuant to this doctrine, a manufacturer's failure to warn about prescription products…extends only to the medical professional implanting it and not to the ultimate user like [plaintiff]") (citations omitted). In order to succeed on a failure to warn claim, a plaintiff must prove that stronger warnings would have caused the physician to take a different course. *Kaiser*, 947 F.3d at 1016 ("The causation question here is relatively straightforward: Would Dr. Bales have used the Prolift device to treat [plaintiff's] condition if Ethicon had provided additional warnings?"); *In re Zimmer*, 884 F.3d at 752 ("[A] plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, [the relevant actor] would have altered behavior and avoided injury").

Defendants do not appear to contend that the warnings in the IFU were sufficient, but instead rely on two points from Dr. Basinski's deposition testimony: (1) that Dr. Basinski was unsure regarding whether she read the IFU; and (2) that, before Ms. Hull's surgery, Dr. Basinski had knowledge of numerous potential risks and complications associated with the TVT-S, and that inclusion of those risks in the IFU for the TVT-S would not have altered her decision to recommend the TVT-S to Ms. Hull in 2008. As to whether she read the IFU, Dr. Basinski testified as follows:

Q: Dr. Basinski, do you recognize this document [the IFU]?

A: Not – not necessarily.

Q: Okay. Do you recall the TVT Secur – every box of the TVT Secur coming with a written piece of paper inside?

A: I cannot recall that either.

* * *

Q: Am I correct that as you sit here today, you don't ever recall reviewing this?

A: I don't recall reviewing or not reviewing it.

Q: Okay.

A: So –

Q: It's possible you did?

A: It's possible I did.

Q: It's possible you didn't?

A: It's possible I didn't.

[Filing No. 23-1 at 29.]

In terms of knowing the risks of the TVT-S, or the use of mesh in general, Dr. Basinski testified that she was aware at the time of Ms. Hull's surgery that there were risks associated with the TVT-S including chronic pain, pelvic prolapse, chronic dyspareunia, mesh erosion or exposure, bleeding, wound complications, new or worsening urinary symptoms such as retention or overactive bladder, failure of the surgery to treat the incontinence, organ or nerve damage, fistula formation, infection, foreign body response to the mesh, vaginal scarring, and contraction of tissue. [Filing No. 23-1 at 28.] She testified that she was aware of these risks because "in general, my training would have included understanding all of those risks with any polypropylene mesh." [Filing No. 23-1 at 28.] Dr. Basinski testified that she believes that in 2008 she was adequately informed of the risks associated with surgery for the TVT-S, and that she shared those risks with Ms. Hull. [Filing No. 23-1 at 28-29.] She also testified:

> Q: If Ethicon had listed each and every risk that you and I just went through a few moments ago in this instructions for use document, would that have in any way affected your decision to recommend the TVT Secur…to Ms. Hull in 2008?
>
> A: No.
>
> Q: Why not?
>
> A: Because those were known risks with any midurethral sling procedure.

[Filing No. 23-1 at 30.]

While Dr. Basinski's testimony is unclear regarding whether she read the IFU – she may have, or she may not have – it is very clear regarding her knowledge of the risks associated with the TVT-S and her lack of reliance on the IFU. In short, even if the IFU had included a warning regarding all of the risks associated with the TVT-S, Dr. Basinski still would have recommended the surgery to Ms. Hull. Indeed, she already knew of those risks through her training. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 728 (N.D. Ill. 2016) (applying learned intermediary doctrine and finding that failure to warn theory failed for lack of causation because "Dr. Larson, the implanting surgeon[,] admits that he has never read the package insert that accompanied [plaintiff's] implant and that…he learned the technique he used to implant the device from his fellowship and training and did not rely on any printed or written material from [defendant]. Because Dr. Larson did not read or rely upon the warnings [defendant] actually provided, Plaintiffs cannot prove that an improved warning – whether about the risks…or about proper surgical technique – would have led to a different outcome in [plaintiff's] case") (quotations and citations omitted); *Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978 (N.D. Ind. 1999) ("[E]ven if the manufacturer provides inadequate information, however, the manufacturer will not be liable if the plaintiff's physician independently knew of the risks and failed to advise the plaintiff").

Ms. Hull points to Dr. Basinski's testimony that she "had no information with regard to Ethicon declining offers from key opinion leaders to conduct pre-market, randomized control trials on the TVT-S"; "had no recollection of being told by anyone at Ethicon that there were studies which showed substantially high mesh exposure and erosion rates associated with the TVT-S as opposed to [an older version]," "had no information from Ethicon regarding tips and tricks being offered to certain surgeons as early as 2007 pertaining to the TVT-S," and "was not aware that Ethicon voluntarily withdrew the TVT-S from the entire continent of Australia in 2007." [Filing No. 28 at 11-12.] Significantly, however, Dr. Basinski was not asked whether – nor did she testify that – knowing any of this information would have changed her recommendation that Ms. Hull undergo the TVT-S surgery.

Finally, Ms. Hull points to her own testimony that had she been informed of the risks associated with the TVT-S, she would not have consented to the surgery. [Filing No. 28 at 12-13.] But the learned intermediary doctrine focuses on what information was provided to the treating physician, and whether having additional information would have changed the physician's treatment, not on what information the patient was given. *In re Zimmer*, 884 F.3d at 752 ("to the extent that [plaintiff's] defective-warning claim is based on Zimmer's duty to warn *him*, it is foreclosed by the learned-intermediary doctrine") (emphasis in original). Ms. Hull's testimony regarding what she would have done is irrelevant to the causation analysis under the learned intermediary doctrine.

Because Ms. Hull has not identified record evidence that Dr. Basinski would have changed her recommendation for the TVT-S surgery had Defendants warned her of additional risks, Ms. Hull's negligence claim based on a failure to warn theory fails as a matter of law and the Court **GRANTS** Defendants' Partial Motion for Summary Judgment on that claim.

b. Design Defect Theory

Defendants do not appear to address Ms. Hull's negligence claim based on a design defect in their Partial Motion for Summary Judgment. [*See* Filing No. 24 at 6-11 (Defendants addressing strict liability design defect claim, strict liability failure to warn claim, negligent failure to warn claim, and negligent manufacturing defect claim, but not negligent design defect claim).] Out of an abundance of caution, however, the Court briefly addresses that claim.

Under Indiana law, a design defect claim requires proof that "the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product…." Ind. Code § 34-20-2-2. Ms. Hull must ultimately show that Defendants owed a duty of care to her in the design of the TVT-S, and that the breach of that duty of care proximately caused her injury. *Kaiser*, 947 F.3d at 1008. A plaintiff need not prove that there was "a cost-effective, safer design" in order to succeed on a design defect claim under the IPLA. *Id.* at 1013. Ms. Hull argues that her expert, Dr. Rosenzweig, has "offered a wealth of expert opinions regarding the defective design of the TVT-S such that, at a minimum, a genuine issue of material fact exists for the jury to decide…." [Filing No. 28 at 8.] Because Defendants have not moved for summary judgment on Ms. Hull's negligent design defect claim, and since Ms. Hull has pointed to evidence which supports her claim in any event, her negligent design defect claim will proceed.

IV.
CONCLUSION

For the foregoing reasons, Defendants' Partial Motion for Summary Judgment is **GRANTED IN PART** and **DENIED IN PART.** The Motion is **GRANTED** as to Ms. Hull's negligence claim (Count I), but only to the extent that claim is based on a failure to warn theory; strict liability – failure to warn claim (Count III); and strict liability – design defect claim (Count V), and those claims are **DISMISSED WITH PREJUDICE**. Defendants' Partial Motion for

Summary Judgment is **DENIED AS MOOT** as to Counts II, IV, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, and XV, and those claims are **DISMISSED WITH PREJUDICE** along with Counts XVII and XVIII.

Ms. Hull's negligence claim (Count I) will **PROCEED**, but as a claim under the IPLA for design defect only.

Date: 3/10/2020

Hon. Jane Magnus-Stinson, Chief Judge
United States District Court
Southern District of Indiana

Distribution via ECF only to all counsel of record